REMARKS

This amendment is submitted in response to the non-final Office Action mailed on July 29, 2005. Claims 1-12, 19-22 and 26-29 are pending in this application. In the Office Action, Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. §112, second paragraph. In response Claims 1, 7 and 19 have been amended. This amendment does not add new matter. In view of the amendment and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claim 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Patent Office alleges that the phrase "less than the enteral administration amount of the medicament" is indefinite.

Applicants have amended independent Claims 1, 7 and 19 to recite, in part, that the claimed chewing gum includes less than a typical amount of medicament than is swallowed by the individual to achieve a bioequivalent effect. Support for the amendment can be found in the specification, for example, at page 6, lines 12-14, page 7, lines 27-32 and page 8, lines 2-4, which discloses that lower amounts of medicaments and agents than is typically consumed or swallowed by an individual can be administered via chewing gum while achieving the same effect or bioequivalence. Applicants have also made several additional clarifying amendments to the claims, which are supported, for example, at page 10, line 15 to page 14, line 10.

As apparent from the specification the invention is intended to apply to a wide range of drugs and agents (page 8, lines 22-33) and one of skill in the art would understand that absolute amounts of the active agents in gum would vary depending upon the agent. While exemplary amounts have been provided in the specification in certain instances, for example at page 9 at lines 1-25; as indicated at page 9, lines 26-31, exact dosing regimens will depend on the agent or medicament. One of skill in the art would understand that for FDA approved drugs, typical amounts would be the approved amounts and the amount used in a gum formulation would clearly be the amount that delivers the bioequivalent of an approved dosage. Where different dosages are approved and used, various gum compositions would deliver bioequivalent amounts for the different approved dosages. For other agents, typical amounts can easily be identified by

one having skill by reading the ingredient listing on a package insert or by testing using various analytical techniques such as chromatography. The specific amount of an agent incorporated into a gum for delivering a bioequivalent amount can be determined by one skilled in the art using available methods. Thus, Applicants submit that those skilled in the art would understand the bounds of the claims when read in light of the specification and Claims 1, 7, and 19 are definite and patentable. Applicant requests that these claims and their dependent Claims 2-6, 8-12, 19-22 and 26-29 be allowed. Based on at least these noted reasons, Applicants believe that Claims 1-12, 19-22 and 26-29 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claim 1-12, 19-22 and 26-29 under 35 U.S.C. §112 is improper and the rejection be withdrawn.

In addition, with regard to the written description requirement, Applicants respectfully note that the subject matter of the claim need not be described literally (i.e. using the same terms or *in haec verba*) in order for the disclosure to satisfy the written description requirement as long as the specification conveys to the artisan that the inventors had possession of the claimed subject matter at the time of filing. *Ex parte Holt*, 19 USPQ2d 1211 (BPAI 1991). Claim limitations can be supported through express, implicit or inherent disclosure. See, MPEP 2163.02.

Nevertheless, the specification explicitly states at page 8, lines 2-4, "it has also been surprisingly found that less medicament or agent can be placed in the chewing gum than is typically orally administered to an individual to achieve an effect and the same bioequivalents can be achieved." (emphasis added.) Thus, the quoted portion of the specification at a minimum in and of itself supports the limitation.

Furthermore, Applicants respectfully submit that the numerous examples and experiments set forth in the specification demonstrate the claimed chewing gum having a bioequivalent effect. In this regard, Applicants also note for the record that the term "bioavailability" is related to bioequivalents. See, *Handbook of Clinical Drug Data*, page 12, 5th Edition. As discovered by Applicants, the administration of the medicament or agent via a chewing gum through the buccal cavity can provide an increased effect than when the same medicament or agent is taken through enteral or oral administration (e.g. swallowed via capsules or tablets). Consequently, a smaller or reduced amount of medicament or agent is needed in the

chewing gum to achieve the same bioavailability or bioequivalent effect in the body of the consumer as a larger amount of the same medicament or agent that is typically swallowed by the consumer. For example, this is demonstrated with the caffeine study of Experiment 2 comparing the bioequivalent effect/bioavailability of caffeine in consumers' bloodstream after chewing caffeine containing gum versus swallowing caffeine pills. These examples demonstrate that less caffeine can be provided in the claimed product than that that is typically ingested, for example through No Doze, and still achieve as good if not greater effect. In fact, Applicants are able to achieve a bioavailability utilizing an oral drug delivery system that approaches that of a parenteral administration.

As further evidence, Applicants have submitted an affidavit under 37 C.F.R. §1.132 ("*Affidavit*" attached hereto as Exhibit A). Applicants respectfully assert that the *Affidavit* provides support for the amended Claims 1, 7 and 19 with respect to the written description requirement. In this regard, the *Affidavit* sufficiently and properly evidences that one having ordinary skill in the art would understand that the Applicants had possession of the claimed inventions at the time the application was filed.

Applicants respectfully submit that the specification clearly provides the necessary support in the written description for the amended claims, and therefore, Applicants respectfully request that the above-identified patent application be passed to allowance.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____
Robert M. Barrett
Reg. No. 30,142
Customer No. 29156

Dated: October 27, 2005